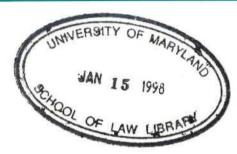
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N E W E T E R Volume IV

Number 3



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Testing and Telling?: Genetic Privacy, Family Disclosure and the Law

redictive genetic testing techniques are developing at a lightning pace. Dramatic technological advances suggest that the greatest impact in genetic testing will result from tests that predict risk for common killers such as cancer and heart disease. While testing may lead



Francis S. Collins

to an impressive reduction in mortality, the use of genetic testing on a scale as vast as anticipated by the Human Genome Project will

undoubtedly create complex legal and ethical problems for the courts.

The L&HCP brought together a distinguished group of nationally recognized experts who presented substantive analyses on the medical, psychosocial, legal, and ethical implications of disclosure, and provided consumer and judicial perspectives, as well.

From the Director

ince the L&HCP has added two important facets to our Program-The Journal of Health Care Law & Policy and the Concentration in Health Law-we have become even more cognizant of the importance of interaction among our program components.

The theme of this issue is synergy-most of the articles highlight the interdependence of selected program components and the way each enhances the other.

I hope you enjoy the issue.

Karen Rothenberg

Presenters included Francis S. Collins, MD, PhD, director of the National Human Genome Research Institute at the National Institutes of Health, who discussed medical implications of the genetic revolution and R. Alta Charo, JD, who delivered the Stuart Rome Lecture, "Genetic Essentialism and the Future of Law."

Also presenting papers were Ellen Wright Clayton, MD, JD from Vanderbilt University, who discussed the legal implications; Allen Buchanan, PhD, from the University of Wisconsin, speaking on the ethical responsibilities of physicians and patients; Caryn E. Lerman, PhD, from the Georgetown University Medical Center (GUMC), who presented empirical data

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Law & Health Care Newsletter

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Director: Karen Rothenberg, JD, MPA

Associate Director: Diane E. Hoffmann, ID, MS

There are a number of law school faculty who contribute to the diversity of the Law & Health Care Program through their teaching and scholarship. Beginning with this issue, we will share some of their selected publications, presentations, and appointments in Faculty Notes: Taunya Lovell Banks, JD Richard Boldt, JD Deborah S. Hellman, MA, JD Stanley S. Herr, JD, DPhil David A. Hyman, MD, JD Susan Leviton, JD Max Stul Oppenheimer, JD Joan O'Sullivan, JD Rena I. Steinzor, JD Deborah J. Weimer, JD, LLM Roger C. Wolf, JD

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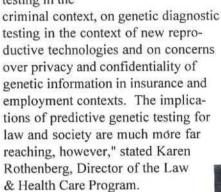
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Testing and Telling Cont. from page 1

on family disclosure of genetic test results; Beth Peshkin, MS, CGS, also of GUMC, who moderated a panel on

consumer
perspectives; and
state Judge
Rosalyn B. Bell,
who discussed
judicial perspectives.

"Most geneticsrelated legal scholarship has focused on the use of DNA testing in the



Rothenberg adds that because predictive genetic testing may determine with some specificity the health risks faced by individuals, as well as their blood relatives, it challenges existing legal, ethical and practice paradigms. The boundaries of privacy between health care professionals, patients and family can be overrun in the rush to diagnose, treat, or prevent the onset of a genetic disease.

Traditional medical ethics and legal rules need to be re-examined to accommodate changing familial rights and responsibilities within the genetics context. The paradigm of individual autonomy in health care supports an individual's right to evaluate the benefits and risks of medical testing, to decide whether to be tested and whether to share test results. However, what is the responsibility of the individual and the provider to share genetic test results with other family members? Is the patient, in fact, the individual or the family unit? When

sharing genetic information, how many generations should be included? What responsibilities will there be to obtain

and share information about genetic predispositions? In certain cases, the mutation cannot be found without testing the affected carrier and other blood relatives. What if some relatives want to be tested and some do not? Can family members keep genetic secrets? Who in the family should contact family members with genetic information? What is the duty of a health

care provider to warn a family member of genetic risk?

Two recent court cases have considered the physician's duty to warn relatives who are at risk of developing a genetic disease. The Florida Supreme Court held that a physician had a duty to tell his patient of the risk to offspring and to encour-



R. Alta Charo

Judge Rosalyn B. Bell

age the patient to share this information with his children. The court clarified, however, that the physician has no duty to warn family members,

reasoning that it would be prohibited by disclosure laws, as well as be impractical, difficult, and place too heavy a burden on the physician. Rather, the court reasoned that the patient ordinarily can be expected to pass on the warning to family members.

More recently, the New Jersey Superior Court held that the physician did have a duty to warn and declined to hold that in all circumstances, the duty to warn will be satisfied by informing the patient. It predicted that if the case went to trial, the court may have "to resolve a conflict between the physician's broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease."

These two cases further highlight the need for better understanding of family relationships, privacy and confidentiality concerns, and realistic expectations in the genetics context.

The Workshop's main goal was to expand scholarship on what the role of the law should be in governing the disclosure of genetic information by health care professionals and individuals to family members. Participants included judges, policy makers and members of the genetics community, who evaluated and critiqued each presentation.

The papers will be published in the Spring/Summer 1998 issue of the University of Maryland School of Law's *Journal of Health Care Law & Policy*.

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Faculty Undertake Diverse Research Projects

Mayday Scholar

n July, Professor Diane Hoffmann, received a grant from the Mayday Scholars fund to conduct a study on pain management and managed care. She along with four other individuals were selected to receive the grant by the American Society of Law Medicine & Ethics. The grant was awarded as part of the Society's initiative to "develop scholarship and expertise in legal, regulatory and financing polices that affect access to effective pain relief." The issue of managed care and pain relief was identified by the Society as a priority topic. Professor Hoffmann's study, already underway, is being conducted in coordination with the national Blue

Cross Blue Shield Association. She will be surveying BCBS plans to identify or determine (1) the level of concern among health plans about pain control and palliative care as issues for their insured populations, (2) activities being undertaken by plans to address issues of pain control and palliative care; (3) the level of plan coverage for pain control and palliative care services; and (4) examples of innovative and best practices by plans to deal with the issues of pain control and palliative care.

Health Insurance Preferences

Professors Diane Hoffmann and Taunya Banks are currently conducting a major study of state employees at the University of Maryland at Baltimore and Coppin State to determine which health insurance plans they have chosen over the past two years, whether they have changed health insurance plans, and, if so what factors influenced their decision to change plans. The survey also asks whether employees have had disputes with their health plans and whether they were satisfied with the way in which the disputes were resolved and their attitudes generally about managed care. The survey was distributed in October, during the State's Open Enrollment season. Hoffmann and Banks are interested in looking at several factors

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L&HCP Faculty Notes

PROFESSOR KAREN ROTHENBERG Publications:

"Genetic Accountability and Pregnant Women," 7 Women's Health Issues 215 (1997)

Selected Presentations:

"Predictive Genetics & Women's Health: Ethical, Social & Policy Challenges," Beyond Hunt Valley: Research on Women's Health for the 21st Century, National Institutes of Health, Bethesda, Maryland (1997)

"Predictions and Precautions: Ethical. Legal and Social Challenges," Li-Fraumeni Syndrome, 31st Patterson Symposium, Patterson Institute for Cancer Research, Manchester, England (1997)

Lecturer, "Gaps and Paradoxes: Challenges for Research Ethics," NIH Clinical Center, Bioethics Program, Bethesda, Maryland (1997)

"Risk, Regulation, and Responsibility: Genetic Testing and the Use of Information, Seminar Series on Genetic Research and Society," American Enterprise Institute for Public Policy Research, Washington, D.C. (1997)

"Discrimination and Legislation," Ethical, Legal, and Social Implications of the Human Genome Project, Dartmouth College, Hanover, NH (1997)

Appointments:

Coordinating Group on Bioethics and the Law, American Bar Association (1997-)

ASSISTANT PROFESSOR DIANE HOFFMANN

Publications:

"Managing the Persistent Patient with Chronic Pain," Case Commentary, 9 Healthcare Ethics Committee Forum 365 (1997)

Selected Presentations:

"Ethics Committees, Lawyers & the Law," Federal Judicial Center Conference on Health Care and the Legal System," Palm Springs, CA (1997)

"The Impact of the Supreme Court's Decisions on Physician Assisted Suicide on Nursing Homes," Annual Meeting, American Association of Homes and Services for the Aging, New Orleans, LA (1997)

"Pain Management and Managed Care," Blue Cross/Blue Shield Northeast Medical Directors' Conference, Annapolis, MD (1997)

"Integrating Elderlaw Into the Health Law Curriculum," The 18th Annual Health Law Teachers Conference, Seton Hall University, Newark, NJ (1997)

ASSISTANT PROFESSOR DEBORAH S. HELLMAN

Publications:

"Is Actuarially Fair Insurance Pricing Actually Fair?: A Case Study in Insuring Battered Women," 32 Harv. C.R.-C.L. L. Rev. 355 (1997)

Selected Presentations:

"Genetic Testing: Legal and Ethical Issues," Federal Judicial Center Conference on Health Care and the Legal System, Palm Springs, CA (1997)

ASSOCIATE PROFESSOR STANLEY S. HERR

Publications:

"Ouestioning the Ouestionnaires: Bar Admissions and Candidates with Disabilities," 42 Villanova L. Rev 501 (1997)

Selected Presentations:

"Aging, Rights, and Disabilities," Keynote Speaker, Vision Conference, University of Wyoming College of Health Sciences (1997)

"Legal Rights and Policy Issues for Adults with Mental Retardation," Johns Hopkins Medical Institutions, Baltimore, MD (1997)

Associate Professor DAVID A. HYMAN

Publications:

"Medicaid, Managed Care and America's

Health Safety Net," (with R. Manski and D. Peddicord) 25 J. Law Med. & Ethics 30-33 (1997)

"Consumer Protection (?), Managed Care, and the Emergency Department," in Achieving Quality in Managed Care: The Role of Law 57-77

Selected Presentations:

"Nonprofit or For-Profit?: Hospital Conversions and Optimal Subsidy Policy," American Public Health Association Annual Meeting, Indianapolis, IN (1997)

"Consumer Protection in a Managed Care World: Should Consumers Call 911?, " Pursuing Health in an Era of Change: Emerging Legal Issues in Managed Care, Thirty- Second Annual Symposium of the Villanova Law Review, Villanova School of Law, Philadelphia, PA (1997)

VISITING ASSISTANT PROFESSOR JOAN O'SULLIVAN Selected Presentations:

"Adult Guardianship and Alternatives," Continuing Education, University of Maryland School of Social Work, UMB (1997)

"Long Term Managed Care in Maryland," Families USA Regional Medicaid Managed Care Conference, Gallaudet University, Washington DC (1997)

"Legal Aspects of Health Care," University of Maryland School of Medicine, Behavioral Sciences Seminar, Baltimore, MD (1997)

ASSISTANT PROFESSOR DEBORAH J. WEIMER

Book Review:

"Ethical and Legal Issues in AIDS Research," published in the Journal of Legal Medicine, Vol. 17, p. 177 (1997)

CLINIC LAW

The law school offers, as part of its regular curriculum, a clinical law program in which faculty members who are practicing attorneys supervise law students in the representation of actual clients. For those students with a general interest in health law, the clinic represents clients in cases involving health care for children, legal issues of the handicapped, mental illness, AIDS and the elderly.

ne engrossing aspect of teaching health law clinic students is watching them struggle to define the limits of a lawyer's role. This is especially difficult when we represent older, vulnerable clients whose competency is tenuous. These clients often have multiple problems, and their legal concerns may be by far the least pressing. Students are often torn between the principles of client centered decision making that we teach, and their strong impulses to solve all of a client's problems and to protect their client from all harm.

Especially with our senior citizen clients, we attempt to respect their autonomy and their right to make their own decisions about their case, despite their physical and, sometimes, emotional fragility. However, when the client's capacity is questionable, we often wonder whether this is the right tack to take. Students are torn between respect for the client's autonomy and paternalism, a tension often present in working with the elderly who have impairments.

A recent case demonstrated this tension clearly. We were referred an estate case in which there was suspected financial abuse. The client was Mr. M., an 83 year old man whose wife of 53 years had recently died. He

by Joan O'Sullivan, JD

owned his own home, and it was not long before a distant cousin, Stan, Stan's girlfriend, and several children had moved in to take care of Mr. M. It was the cousin who had asked for legal help: he wanted Mr. M. to make a will, leaving the house to him in return for his care giving.

Mr. M.'s daughter in Florida had heard about this and was concerned. She also worried about Mr. M.'s finances. He had worked for the railroad for many years and had a good monthly pension, as well as some insurance proceeds from his wife's death. She suspected that Stan was living off this money and had asked the referring agency for an investigation of financial abuse and for protection for Mr. M.

Mr. M. had not asked for anything. My student, Kate, and I discussed this fact before we went to interview him at his home. We talked about how we could determine whether Mr. M. was competent, and how to set up the interview so that we could speak to him alone. Kate was well aware that the request for representation had to come from Mr. M., and that it was he who had to sign the retainer agreement.

This first interview was very difficult, as interviews out of the controlled setting of the law office often are. The cousin and two young children were present, and other children came home from school while we were there. We had explained our need for a confidential setting, and we were directed to the dining room table while the family went out on the porch. There was very little privacy, however, as members of the household hovered around the open porch window and

came and went from the kitchen. Mr. M. looked around constantly to see who was listening.

Mr. M. seemed oriented, aware of who we were and why we were there. When Kate asked if he wanted any legal help, he said no. When she pointedly asked if he wanted to make a will, he said no, emphatically. He said he thought his daughter would get his house when he died. Even if he did not write a will, this was true. This seemed to be the end of our case. If he was competent and did not want our help, there was little we could do.

We called Stan in to explain this. He blew up, outraged that we refused to help. He insisted that at least we help him find out if there was any mortgage life insurance on the life of Mr. M.'s wife, since Stan had been stymied in his attempts to do so. Mr. M. agreed that we could do this, and he signed a limited retainer agreement.

Kate did a good job of investigating the situation. She collected documents from Mr. M. and Stan, and soon learned a great deal about his financial picture. She discovered that large amounts of money had disappeared from Mr. M.'s bank account since his wife's death, and that his pension check was being withdrawn every month as soon as it was deposited. She planned to explain this to Mr. M. and the results of her fruitless search for mortgage insurance. She was convinced that when she told Mr. M. about what was happening to his money, he would want her to take all actions possible to protect his assets.

She talked to a worker from Adult Protective Services (APS) who was investigating an anonymous complaint of abuse, and persuaded the worker that Mr. M. did not need a guardian, but that he could appoint an agent in a

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In The Health Law Clinic Cont. from page 5

power of attorney or ask for a representative payee for his Railroad Retirement check. She was confident that he would do so. Who wouldn't?

Kate arranged for Mr. M. to come to our office for this next appointment. She explained to Stan that she would see Mr. M. alone first, and then she would speak to Stan if Mr. M. agreed.

I was copying some papers when Kate found me. "I can't get him out of the waiting room!" she said. "Mr. M.—he won't budge from Stan's side. He refuses to come with me alone."

Mr. M. was sitting as if glued to Stan's arm. Stan was a large imposing figure, and was glowering at us. Mr. M. looked small and scared beside him. I asked Mr. M. if he would like to come to the interview room with us. He looked at Stan and said no.

I tried to reassure him, explaining that we would bring Stan in later and tell him everything we had said if he wanted that. Mr. M looked at Stan and said no.

I asked Mr. M. if there was something he was afraid of. Mr. M. looked at Stan and said no. Then Stan spoke up, insulted that I was implying that Stan had said or done something to Mr. M. to intimidate him. Stan said he had just one concern and that was his family's security.

Kate tried again to persuade Mr. M. to come with her, but finally I intervened and said that if Mr. M. did not wish to talk to us, he was free to go. I explained that if he did not want our representation, we would close the case. The pair rose and headed for the elevator. Kate and I headed for my office to debrief.

She was frustrated and upset, and positive that Mr. M. was afraid of Stan and that something very bad was happening to him. She wanted to call the APS worker to make certain that she vigorously pursued her investigation, and said she was sorry that she had dissuaded the worker from filing for guardianship. She became even more frustrated when she ran into the brick wall of client confidentiality.

Without Mr. M.'s consent, there was

nothing Kate could tell APS. We examined the confidentiality rule carefully, but reluctantly admitted that this situation did not fit any of the exceptions. We looked at the statute for mandatory reporting of abuse of vulnerable adult; lawyers were not included in the list of professionals who must report. And yet, Kate could not accept that her role had ended. Her desire to protect Mr. M. was overwhelming. Gone was her belief that he was competent, and gone was her willingness to let Mr. M. direct the course of the case. She felt he needed help and that she had to do something.

I had to admit that I felt much the same way. Kate and I spent some time scheming about indirect ways of reporting what we knew to APS, to prod them into investigating further. We could not think of a single way to help him ourselves, for each time we had to ask, "Where would we get the authority to act, if not from the client?"

We decided to think about the problem overnight and meet again the next day. During that time I wondered how much of my feeling was a desire to protect this client and how much was simply a desire to win, to prevent Stan, with or without Mr. M.'s compliance, from taking advantage of the old man. I wondered why we were willing to believe our client competent when he wanted our help, and unwilling to believe him competent when he did not?

In the end, we decided there was little else we could do. Kate gradually came to accept that after all we are only lawyers, not miracle workers. We are merely agents of our clients. We can employ, interpret and explain the law to the advantage of those clients, but we derive all our authority to act from the client. If the client does not want to be saved, our hands are tied.

Before we closed the case, we devised a careful script for Kate to use when returning a call to the APS worker. She told her that she could not discuss the case further because we no longer represented Mr. M. and that we were bound by the rules of confidentiality. Then she listened as the worker talked about her own distrust of Stan and about her next steps, which

seemed to include a petition for guardianship. Kate heard enough to allay some of her fears for Mr. M., but she intends to keep checking the court docket to search for that guardianship filing.

Faculty Research Projects Cont. from page 3

that may influence health plan choice. In addition to factors that have been looked at in other studies, e.g.. income, health status, family status, cost of plan, premiums, deductibles, etc., they will also be looking at race and medical expertise, which have not been a significant focus of other studies on this topic. The University of Maryland's Baltimore Campus includes the University's schools of medicine, nursing, dentistry and pharmacy and Coppin State has a prédominantly African American faculty and staff.

Greenwall Foundation

In November, Professor Hoffmann received a planning grant from the Greenwall Foundation to determine the shortfall between the current level of knowledge and skills of those individuals doing bioethics consults and those proposed in the guidelines put forth by the Society for Health and Human Values Task Force on Standards for Health Care Ethics Consultation.

The Task Force guidelines were proposed this fall, but their "need" has not been empirically documented nor evaluated in terms of ultimately improving the effectiveness of the performance of ethics committees.

This issue is especially relevant to the state of Maryland which, in 1987, enacted a law requiring that all hospitals have "patient care advisory committees" or ethics committees, as they are more commonly called. The law was extended to include nursing homes in 1990. Committee quality in Maryland is uneven and yet committees have considerable authority under the state's Health Care Decisions Act to make health care recommendations affecting life sustaining treatment and other medical treatment decisions regarding incapacitated patients.

Spotlight on ...

HEALTH LAW PRACTICUMS
AND EXTERNSHIPS: The National
Institutes of Health

by Malka Scher, 3D

fter 17 years as a biochemist in a medical school setting I hoped that law school would bring a new focus and direction for applying my science background. Many times in the first two years of school I second-guessed leaving the security of the scientific research environment. However, once I began taking health law courses I started to see the possibilities. Then, every career option seemed exciting. Hands on experience helped me to define my career goals.

My first opportunity for real world health law experience was a practicum at the National Institutes of Health (NIH) Office of the General Counsel (OGC). The OGC is responsible for all the legal concerns of all the institutes which comprise the NIH. Issues may arise that are related to clinical care, to research, or to the awarding of grants to outside investigators. The legal issues are as diverse as property and employment law, scientific misconduct, or patent law. My supervising attorney in the OGC was primarily responsible for issues relating to technology transfer, an increasingly important area in law. The goal of technology transfer is to take new technology from the laboratory to applications for public use.

With respect to NIH, the government is not involved in commercialization, so any basic research results which might have public health benefits must be further developed by private entities. While in the OGC I had the opportunity to review a variety of agreements between NIH and private entities for research collaboration and for technology transfer.

I must confess that I had little understanding of the significance of the provisions in these agreements.

To further develop my skills I participated in an externship at the National Cancer Institute (NCI) in the Technology Development and Commercialization Branch (TDCB). The TDCB is responsible for representing NCI scientists in forming agreements with private entities for transfer of materials and for research collaborations. Clinical trials agreements and agreements for screening of compounds supplied by outside entities are also negotiated by the TDCB. Pharmaceutical companies and biotechnology companies are interested in collaborations and other agreements with NCI because of the network of clinical testing sites that NCI has in place and because of the outstanding research capabilities of NCI scientists and physicians.

My most significant responsibilities at the TDCB included the negotiation and drafting of Material Transfer Agreements which provide for the sharing of research materials between outside parties, generally non-profit institutions, and government scientists. I was also fortunate to be given the opportunity to negotiate and draft more complex Material Transfer Agreement - Cooperative Research and Development Agreements.

While at the TDCB my understanding of the provisions in these agreements increased dramatically compared to the time I was at OGC. In negotiating these agreements I acted independently in interactions with the NCI scientists many of whom are world renowned and are at the forefront of development of new research or clinical methods.

Since, unlike private entities, certain provisions in NIH agreements are governed by federal statute, regulations, and NIH policy, it was necessary for me to learn the pertinent substantive law. With this background and with supervisory approval I drafted the appropriate modifications to standard agreements. The

The Law & Health Care Program's Health Law Practicum Program provides an opportunity for students interested in health law to obtain credit by working for organizations and government agencies dealing with health care issues. Students spend 10 to 20 hours at their placement and additional hours throughout the semester in the classroom participating in The Health Law Practice Workshop. Placements have included the American Nurses Association; FDA; Johns Hopkins Hospital, Office of the General Counsel; Med-Chi of Maryland; Medlantic Healthcare Group; National Health Law Program; NIH; U.S. Senate Special Committee on Aging; University of Maryland Medical System, Office of the General Counsel; and the Office of the Attorney General, General Litigation Unit and Medicaid Fraud Unit.

The Program has also offered seven full semester externships—The National Health Law Program externship in Washington, D.C.; The University of Maryland externship, located in University Hospital's General Counsel's office; Blue Cross/Blue Shield of Maryland (BCBSM), The Federal Trade Commission, The Health Care Access and Cost Commission; the NIH General Counsel's Office; and the Women's Legal Defense Fund in Washington, D.C.

amount of responsibility that I was given contributed immeasurably toward developing proficiency in negotiation and toward evaluating transactional law as a possible career choice.

Since I have had experiences at two different NIH offices, it is possible to compare these different legal positions within the framework of a single federal agency. Both the nature of the legal work and the breadth of the legal work differ in the two offices. It appears to me that in the OGC NIH attorneys spend considerable time researching, analyzing, and applying the law. Issues may arise which require the legal staff to discuss policy changes

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Student Health Law Organization (SHLO) News

In early October, representatives of the Student Health Law Organization participated in the annual Alzheimer's Memory Walk, earning \$130.00 for the Alzheimer's Association.

On November 20, 1997, SHLO sponsored a career panel at which four attorneys presented students with diverse views on the practice of law in a variety of settings. Attorneys participating in the panel included: Jane Weaver, JD, MN, FNP, RN of the American Nurses Foundation; Thomas Doherty, JD, Medlantic Healthcare Group; Roy Mason, JD, Mason, Ketterman & Morgan; and Nancy Tennis, JD, Assistant Attorney General from the Department of Health and Mental Hygiene.

The program was organized in a "day in the life" type format and about thirty students attended. A reception was held after the event to allow those attending an opportunity to talk informally.

In another area, SHLO President, Chris Coffin has information regarding a new program designed to teach elderly persons about advance directives—an opportunity for SHLO members to perform some legal health care work for the community. Contact the program office or Chris at ccoffin@umabnet.ab.umd.edu.

SHLO officers for the 1997-98 academic year are: Chris Coffin, President; Dan Gaskill, Vice-President; Dan Alexander, Secretary; and Mike Imber, Treasurer.

Spotlight On Cont. from page 7

with the top administrative officials at NIH. Thus, it seems the attorneys at OGC are quite influential and the questions they analyze may be quite significant.

In contrast, the TDCB attorneys practice transactional law and have a more narrow focus on transactions relating to technology transfer. The attorneys work much more closely with individual scientists and discussions of new technology are common in the office.

Even after completing the practicum and the externship and participating in the Health Law Practice Workshop, am still analyzing career options. Although I once thought that a career choice meant following a straight and narrow path to a goal set early in life, I now see that for me, at least, defining and adjusting careful choices is a continuing, life-long process.

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